K071380

510(k) SUMMARY

AUG 20 2007

SOLANAS ™ Posterior Stabilization System
510(k) SUMMARY
May 2007

Company: Alphatec Spine, Inc.
2051 Palomar Airport Road#100
Carlsbad, CA 92011 USA
Telephone: (760) 431-9286
Fax: (760) 431-9132

Contact Person: Paula Morgan, Director of Regulatory Affairs/Compliance

Trade/Proprietary Name: SOLANAS ™ Posterior Stabilization System

Common Name: Spinal Interlaminal Orthosis Fixation

Classification Name: Spinal Interlaminal Orthosis Fixation (888.3050)
Orthosis, Spinal Pedicle Fixation for Degenerative Disc Disease (888.3070)

Product Description:

The SOLANAS III™ Posterior Stabilization System is a spinal fixation system intended to improve stability of the cervical and thoracolumbar area of the spine (C1-T3).

Indications for Use:

It is intended that this device, in any system configuration, be removed after the development of solid fusion mass. Hook components are indicated for use at C1-C7. Polyaxial screws are limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. These screws are not intended for placement in the cervical spine. The components in the Solanas Posterior Stabilization System can be linked to the components in the Zodiac Polyaxial Spinal Fixation System offered by Alphatec Spine using the Axial Rod Connectors, Parallel Rod Connectors or Transitional Rods

- Degenerative disk disease (DDD), defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Atlanto/Axial fracture with instability

- Revision of previous cervical spine surgery
- Tumors

Substantial Equivalence:

The SOLANAS III™ Posterior Stabilization System is substantially equivalent to the following predicate devices:

Trade/Proprietary Name	Manufacturer	Clearance
SOLANAS™ Posterior Stabilization System	Alphatec Spine, Inc.	K052201

Performance Data:

Mechanical and dynamic testing of the posterior stabilization system was performed. The test results demonstrate that the mechanical performance of the SOLANAS III™ Posterior Stabilization System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2007

Alphatec Spine, Inc.
% Ms. Paula Morgan
Director of Regulatory Affairs & Compliance
2051 Palomar Airport Road, #100
Carlsbad, California 92011

Re: K071380
Trade/Device Name: SOLANAS™ Posterior Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWP, MNI
Dated: July, 30, 2007
Received: August 1, 2007

Dear Ms. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bucher
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K071380

Device Name: SOLANAS ™ Posterior Stabilization System

Indications for Use:

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- Tumors

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number_____